

## **ANASTOMOSIS DEVICE AND RELATED METHODS**

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### **Cross-Reference to Related Applications**

The present non-provisional Application claims the benefit of commonly assigned provisional Application having serial number 60/405,140, filed on August 22, 2002, and entitled SURGICAL STENT DEVICES AND METHODS, which Application is  
10 incorporated herein by reference in its entirety.

### **Field of the Invention**

The present invention generally relates to methods of reconnecting urethra and bladder tissues after a radical prostatectomy, and related devices. Particular  
15 embodiments of the invention relate to methods and devices for performing a vesico-urethral anastomosis.

### **Background**

In a radical prostatectomy, the surgeon removes all or most of the patient's  
20 prostate. Because the urethra travels through the prostate immediately before reaching the bladder, the upper part of the urethra is removed in the surgery. The procedure leaves a severed urethral stump and a severed bladder neck. To restore proper urinary functions, the bladder and the urethra must be reconnected.

Conventionally, a surgeon may execute delicate suturing operations with tiny, fine  
25 needles to reconnect these anatomical bodies. Installation of sutures, however, with a needle, to connect the severed tissues, can be a difficult and often technique-sensitive task. Many factors can make this task difficult, including a very small amount of tissue to work with (at the urethral stump and at the bladder neck), proximal ureters at the bladder, and a proximal nerve bundle and sphincter at the urethral stump. All of these  
30 add up to a complicated and delicate suturing procedure that, if not performed properly, could result in complications such as leakage, difficulty in healing or failure to heal, incontinence, or impotence. Specific problems include necrosis of the sutured tissues;

stricture of the urethra, which impedes the flow of fluid through it; and a urethra-bladder connection that is not fluid-tight. In addition, methods of suturing the urethra to the bladder allow for accidental or inadvertent piercing of the nearby neurovascular bundle, which can cause incontinence or impotence.

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### Summary

The invention relates to an anastomosis device that includes a catheter body and tissue approximating structure. The tissue approximating structure can be used to cause or maintain contact between severed portions of tissue to allow or cause the severed  
10 tissue surfaces to heal together, instead of using sutures. The device may be used, for example, in performing procedures such as a vesico-urethral anastomosis in association with a radical prostatectomy, or with an end-to-end urethral anastomosis. Advantageously, the device, including the tissue approximating structure, can be left installed during the healing process to function to allow the tissue to heal while at the  
15 same time functioning to drain urine from the bladder.

Preferred tissue approximating structure may be remotely actuatable from a retracted position (e.g., within the device) to a position of use, external to the device. As an advantage, embodiments of the tissue approximating structure can be moved and adjusted remotely (e.g., using a an actuating mechanism at the proximal end of the  
20 device) during a surgical procedure. The device, overall, thus allows a surgeon to position and re-position a tissue approximating structure during a procedure to effect optimal positioning of the tissue approximating structure and of the tissue.

Embodiments of anastomosis devices of the invention, in addition to the tissue approximating structure, can include features and structures that function to drain the  
25 bladder, e.g., through a drain lumen, while at the same time functioning as a tissue approximating structure that causes contact between severed tissue to allow the severed tissues to heal together. Methods of the invention can use such an anastomosis device, including both a draining function and a tissue approximating function, to accomplish healing of the anastomosis, without sutures, and draining of the bladder, with the single  
30 anastomosis device and preferably without removing or replacing the device during or after the procedure until healing is complete. The anastomosis device can be installed

during or after a radical prostate removal procedure, and can remain installed with the bladder-draining function and the tissue-approximating function in effect until the anastomosis is completely healed and the severed tissue, e.g., bladder and urethra, are re-connected. Thus, an advantage associated with inventive methods and devices can be  
5 that the anastomosis device performs dual functions when installed during and following an anastomosis procedure, of draining the bladder and functioning as a tissue approximating structure, at the same time.

Also advantageously, inventive methods and devices avoid the need to use sutures to connect severed tissue such as a bladder neck and urethral stump. The ability to avoid  
10 sutures provides very significant advantages of avoiding the potential for damage to surrounding tissues and nerves that can be caused by installation of sutures using a needle. Such damage can include, for example, damage to ureters at the bladder or damage to the sphincter or nerves located in the perineal floor. Damage to any of these tissues has the potential to cause incontinence or impotency. Additionally, installing  
15 sutures is a difficult and technique-sensitive process that must be performed in a confined space and that would be avoided if possible based on other alternatives. Thus, the invention offers the very significant advantage of eliminating the need to use sutures to re-attach severed tissues, and the attendant potential damage to those sensitive proximal tissues and nerves and the possibility of incontinence or impotency.

20 In another respect, the inventive methods and devices, by eliminating sutures, can significantly reduce the amount of time required to perform an anastomosis procedure. For example, the amount of time for suture installation can be in the range of from 20 to 30 minutes up to an hour, depending on the type of procedure. A suturing step of a retropubic procedure, for example, may take 20 or 30 minutes, or up to an hour for a  
25 laparoscopic procedure. This amount of time may be significantly reduced, according to the invention, due to the elimination of a suturing step. Reduced procedure time creates the attendant advantages of reduced patient time under anesthesia, which can reduce the costs and complications caused by anesthesia, as well as related general costs.

According to the present description, the term “distal end” refers to a portion of  
30 an anastomosis device that is inserted into a body during an anastomosis procedure and that then becomes located in the region of the bladder, urethra, urethral stump, and

perineal wall. The term “proximal end” refers to a portion of an anastomosis device that is opposite from the distal end, including a portion that remains exterior to the body during use.

5       The terms “tissue approximating” and simply “approximating” refer to a process of bringing or holding body tissues in contact for healing. Examples include: the process of bringing severed surfaces of a bladder neck and a urethral stump, or two opposing severed urethral tissues, into contact for healing; and the process of holding severed surfaces of a bladder neck and a urethral stump, or two opposing severed urethral tissues, together for healing.

10       An aspect of the device relates to an anastomosis device comprising a hollow, elongate, flexible catheter body having a proximal end and a distal end; an inflatable balloon at the distal end; a drainage lumen connected to the distal end; and tissue approximating structure on the catheter body on a proximal side of the balloon at a location to contact severed tissue during an anastomosis procedure.

15       Another aspect of the invention relates to an anastomosis device comprising a hollow elongate flexible catheter body having a proximal end and a distal end; an inflatable balloon at the distal end and inflation means for inflating the balloon; drainage means connected to the distal end for draining urine from a bladder; and tissue approximating means on the catheter body on the proximal side of the balloon for holding  
20       severed tissue in contact for healing.

      Another aspect of the invention relates to a method of performing urethral anastomosis. The method comprises inserting a portion of an anastomosis device into the urethra, the anastomosis device comprising tissue approximating structure and a distal end comprising a balloon; inflating the balloon in the bladder; and using the tissue  
25       approximating structure to hold severed tissue together. Preferably, the device further comprises drainage apertures for draining a bladder and the method comprises draining a bladder.

      Yet another aspect of the invention relates to a method of performing a urethral anastomosis. The method comprises severing a urethra to leave opposing severed  
30       urethral tissues; inserting a distal end of an anastomosis device through the urethra and into the bladder, the anastomosis device comprising tissue approximating structure and a

balloon; inflating the balloon inside of the bladder, and holding the opposing severed urethral tissues together in healing contact using the tissue approximating structure. Preferably, the device further comprises drainage apertures for draining a bladder and the method comprises draining a bladder.

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### **Brief Description of the Drawings**

Figure 1 is a schematic view to illustrate general aspects of radical prostate removal.

10 Figures 2 and 2a schematically illustrate an embodiment of anastomosis devices according to the invention.

Figures 3 and 3a schematically illustrate an embodiment of anastomosis devices according to the invention.

Figures 4 and 4a schematically illustrate an embodiment of anastomosis devices according to the invention.

15 Figures 5 and 5a schematically illustrate an embodiment of anastomosis devices according to the invention.

Figures 6 and 6a schematically illustrate an embodiment of anastomosis devices according to the invention.

20 Figures 7 schematically illustrates an embodiment of anastomosis devices according to the invention.

Figure 8 schematically illustrates an embodiment of an anastomosis device of the invention.

25 Figures 9, 9a, 9b, and 9c schematically illustrate an embodiment of an anastomosis device and a method of the invention. Figures 9b and 9c are close-up schematic illustrations of portions of figures 9 and 9a, respectively.

All drawings are not to scale.

### **Detailed Description**

30 An anastomosis device useful according to the invention can be any anastomosis device that can be useful in the practice of an anastomosis method described herein, e.g., an anastomosis method associated with a radical prostatectomy. An example of a useful

design, generally, is the type sometimes referred to as a Foley catheter that has been constructed to include modified features as also presented in the present description including tissue approximating structure.

An anastomosis device of the invention typically includes a hollow, elongate, flexible catheter body having a proximal end and a distal end. An inflatable balloon can be located near the distal end, and an inflation lumen for inflating the balloon can extend to the balloon along the catheter body, e.g., along a portion or all of the catheter body from the proximal end to the balloon. During use, the balloon can rest against the neck of the bladder to prevent urine from entering the neck and to prevent urine from contacting the anastomosis site. Urine at the anastomosis site has the potential to cause difficulties in healing or to cause a stricture, among other deleterious effects. With the balloon blocking the bladder neck during use, urine will pool in the bladder and can be drained from the bladder, for example, using one or more draining apertures at the distal end of the anastomosis device connected to a drainage lumen. A drainage lumen can extend from one or more drainage apertures near the distal end, e.g., from apertures at the distal end to a location that is at or near the proximal end. As a particular example, a port may be present at the proximal end to connect the drainage lumen to a urine collection device.

Overall, an anastomosis device can contain various lumens (e.g., for inflating a balloon, for drainage, for containing actuating mechanisms for tissue approximating structure, etc.) and actuating mechanisms running along at least a partial length of a catheter body. The mechanisms and lumens can be arranged in any useful configuration such as coaxially, side-by-side, or according to any other useful configuration. A lumen or a mechanism (e.g., actuating mechanism) that runs along at least a portion of the length of the catheter body may be diverted at the proximal end of the catheter body to a port that provides access to the lumen or mechanism during use, as is known.

According to the invention, the anastomosis device includes tissue approximating structure that can be used to place or hold a cut or severed tissue or tissue surface in place for healing while the catheter is installed. Referring to figure 1, a radical prostatectomy procedure includes removal of the prostate 10 (indicated in dashes) and urethra 8 (also in dashes), leaving bladder 2 with bladder neck 4 having a severed tissue surface 6 at one end of removed urethra 8, and a urethral stump 12 extending from perineal floor 14, with

urethral stump 12 having severed tissue surface 16 opposing the severed surface 6 of bladder neck 4. Referring to figure 9, an end-to-end urethral anastomosis procedure includes a step of severing the urethra 8, below perineal wall 14, to leave two opposing severed urethral tissues 8a and 8b. While the following description presents inventive  
5 devices and methods primarily in the context of vesico-urethral anastomosis relating to radical prostatectomy, it will be apparent, and is also described, that the invention can be applied to a variety of other procedures that benefit from tissue approximating structures and in particular where a fluid flow is also desired, such as drainage of urine. A specific example is an end-to-end urethral anastomosis procedure.

10 A tissue approximating structure according to the invention can be a structure of the device that can be used to cause contact between severed tissues, such as severed urethral tissues, or such as severed tissue of the bladder or bladder neck with severed tissue of the urethral stump or perineal floor, or alternatively or additionally to hold  
15 severed tissue surfaces in contact with each other for healing. The tissue approximating structure may include, for example, one or multiple balloon or balloon-like structures that can be placed against the inside of the bladder or underneath the perineal floor to bring the severed bladder neck tissue into contact with the severed tissue surface of the urethral stump. Alternately, the tissue approximating structure may include elongate structures  
20 such as a needle, tine, prod, probe, or the like, which may have a blunt or a sharp end and may movably extend or protrude from an aperture in a flexible catheter body at a location where the structure can function as an approximating structure, e.g., at the distal end of the device where the structure will be near the bladder or perineal wall (when installed), or at a severed urethra below the perineal floor (when installed). Combinations of balloons and elongate structures may also be useful in certain applications. The tissue  
25 approximating structure does not require and can preferably exclude sutures and any component or structure designed to function in combination with a suture or suturing device such as a needle.

An example of a useful tissue approximating structure can be in the form of a sharp or blunt elongate structure (e.g., a sharp-ended needle or tine) that can be movably  
30 extended from an aperture at a distal end of, or at a length of, a catheter body, to thereby contact and optionally penetrate into or through one or more of a tissue of the bladder,

bladder neck, urethra, bulbar urethra, urethral stump, or perineal floor, to place opposing severed tissue surface into contact for healing, and preferably also to hold the tissues in contact with each other during the healing period. Certain embodiments of the invention can include sharp or blunt elongate tissue approximating structure (e.g., a sharp-ended  
5 needle or tine) that can be movably extended from an aperture at a distal end of a catheter body to place opposing severed tissue of the bladder neck into contact with a severed tissue surface of the urethral stump, or *vice versa*, and preferably also to hold the tissues in contact with each other during the healing period.

Advantageously, in one embodiment, a tissue approximating structure may  
10 include one or more sharp elongate, straight or curved, fine metal tines that movably extend from the distal end of the catheter body at a location to allow contact and optionally penetration of the urethral stump proximal tissue in the adjacent perineal floor, urethra, or bulbar urethra. In this form, in addition to causing contact between the severed tissue surfaces of the urethral stump and the bladder neck, preferred elongate  
15 tissue approximating structure may also accomplish the desirable effect of re-exposing the urethral stump from the perineal floor by pressuring the urethral stump from below. As is common with vesico-urethral anastomosis procedures that include sutures, re-exposing the urethral stump after the urethra is severed can be useful because of the often very small amount of tissue associated with the urethral stump, and because of the  
20 tendency of the urethral stump to draw into the perineal floor.

As mentioned, certain preferred embodiments of tissue approximating structures can be movable, e.g., from a retracted or withdrawn position inside of the catheter body (e.g., for tines or needles) or a non-inflated position (for a balloon), to an employed or extended or otherwise “non-retracted” position. In the employed position, wherein the  
25 tissue approximating structure extends beyond the dimension (diameter) of the catheter body, e.g., as with a tine extending through an aperture in the catheter body wall, the tissue approximating structure can be positioned to contact a tissue and facilitate healing between a severed tissue and another severed tissue.

In general, a tissue approximating structure can include any structure that can be  
30 incorporated into or along the catheter body and can be manipulated, e.g., using a mechanism extending along the catheter body, to place or hold severed tissues in contact



for healing. An anastomosis device according to the invention can have one or multiple tissue approximating structures, optionally multiple structures positioned at different distances along the length of the catheter body at one or more locations that allow the tissue approximating structures to contact and place pressure on opposing severed tissue surfaces when the anastomosis device is installed during an anastomosis procedure and afterward, for healing. For placing and holding severed bladder and urethral stump tissues, tissue approximating structure can be located at a suitable length along the catheter body, such as at the distal end where the tissue approximating structure will contact those tissues when installed. For placing and holding severed urethra tissue below the perineal wall, tissue approximating structure can be located further from the end of the device, at a suitable length along the catheter body to contact urethral tissue below the perineal wall when installed.

Exemplary tissue approximating structure may be in the form of a rigid elongate structure that moves from a retracted position (e.g., inside of the catheter body) to an extended position through apertures in the catheter body, such as a movable, elongate, tine or needle type structure. Such a tine or needle structure may include a pointed end to penetrate into or through a tissue. Exemplary elongate structures can be positioned to movably engage apertures in the catheter wall through which the elongate structures can be extended or retracted. Optionally, a guide such as a metal, ceramic, rigid plastic, or polymeric guide can be placed at the aperture between the catheter body wall and the movable elongate structure.

Alternatively, the tissue approximating structure may include one or two balloons that can be positioned to cause contact of two opposing severed tissue surfaces. For example, two balloons may be located to contact the opposite sides of a bladder wall and a perineal floor, one balloon in the bladder and the other below the perineal floor, at a spacing that maintains contact between a severed bladder neck tissue and a severed urethral stump.

In certain preferred embodiments, a tissue approximating structure may comprise multiple, (optionally) opposing sets of elongated structures such as rigid or semi-rigid tines, needles, or the like, which may be straight or curved, and which may optionally include a sharp pointed tip to penetrate into or through a bladder neck, bladder wall,

perineal floor, urethra tissue, bulbar urethra, urethral stump, or any other tissue that can be brought into contact or held together by devices or methods described herein. For example, one or a set of tines may be located at positions along the catheter body where tissue approximating structure can be used to contact severed tissue or tissue proximal to severed tissue, to bring together and hold in place severed tissue for healing with a corresponding severed tissue. As one specific example, an anastomosis device according to the invention may include multiple sets of elongate tissue approximating structures including a first set of movable distal tissue approximating structures positioned to extend through apertures in the hollow catheter body, the distal tissue approximating structure located on the proximal side of the balloon, and a second set of movable proximal tissue approximating structure positioned to extend through apertures in the hollow catheter body, the proximal tissue approximating structure located on the proximal side of the movable distal tissue approximating structure. Each tine or set of tines can be extended independently and remotely, for example by operation of an actuating mechanism such as connected wire or shaft that runs through or along the length of the catheter body.

According to certain presently preferred embodiments of the invention, a tissue approximating structure may comprise a balloon located at the distal end of the device, the balloon being positioned inside of the bladder during use. Figures 2 and 2a illustrate such an embodiment of an anastomosis device of the invention, installed for use within urethra 8 and bladder 34 following removal of a prostate (not shown).

Referring to figure 2, a prostate has been removed to leave a severed urethral stump tissue 22 and opposing severed bladder neck 24. Anastomosis device 20 is installed through urethral stump 22 and bladder neck 24. The device 20 comprises a catheter body 21 and balloon 26 located at the distal end 28 of the device. Preferably and as shown, the device also includes drain lumen 23 and drain apertures 29 located between the tip 25 of the distal end of the device 20 and balloon 26. Balloon 26 is inflated, after insertion into the bladder 34, by a flow of fluid through balloon lumen 30. Pressure (e.g., traction as shown by arrow 31) can then be applied through the length of device 20 to produce a pressure against the inside of bladder 34 from inflated balloon 26. Referring to figure 2a, balloon 26 can be brought to place pressure on the interior of the bladder 34 and draw the severed bladder neck tissue 25 into contact with severed urethral stump

tissue 27. The surface of severed bladder neck tissue 25 aligns automatically with the surface 27 of severed urethral stump 22, around and along the axis of the catheter body 21, provided that no gap exists between the surfaces 25 and 27 of the respective severed tissues.

5 In related embodiments of devices according to figures 2 and 2a, the anastomosis device 20, which in figures 2 and 2a uses balloon 26 as a tissue approximating structure, may optionally and preferably include additional components or features as part of the tissue approximating structure. As an example, figure 3 shows how additional tissue approximating structure may be located along the length of the catheter body 21, at a  
10 location that will place the structure at or below the urethral stump 22 or the perineal floor 31. Such additional tissue approximating structures may be in the form of one or preferably multiple elongate metal tines 33 (three are shown, in the retroacted position) having sharp ends to penetrate into the urethral stump, perineal wall bladder tissue urethral tissue, or other location that is useful to draw or hold together severed tissue.  
15 Located to exit the catheter body 21 through apertures (not shown) to contact tissue at or proximal to the urethral stump 22 or perineal floor 31, the tines 29 may extend from the catheter body 21 at a position (when installed, with the bladder drawn down to the perineal floor) below or proximal to the urethral stump 22 or perineal floor. By extending from an aperture at that location, the tines (or another form of tissue approximating structure) may produce pressure against the urethral stump 22 in a  
20 direction that pushes the urethral stump toward bladder neck 24.

Referring still to figure 3, the prostate (not shown) has been removed to leave a severed urethral stump tissue 22 and opposing severed bladder neck 24. Anastomosis device 20 is installed through urethra 8, urethral stump 22, and bladder neck 24. The  
25 device 20 comprises balloon 26 located at the distal end 28 of the device. Preferably and as shown, the device also includes drain lumen 23 and drain apertures 29. Balloon 26 is inflated and pressure (e.g., traction 31) is applied through the length of device 20 to produce a pressure against the inside of bladder 34 (see figure 3a) from inflated balloon 26 to place the severed bladder neck tissue 25 in contact with severed urethral stump  
30 tissue 27. As shown in figure 3a, the surface 25 of the severed bladder neck aligns automatically with the surface 27 of the severed urethral stump, around and along the

axis of the catheter body 21. Also shown in figure 3a are tines 33 that extend from catheter body 21 at a position below perineal floor 35 and penetrate into perineal floor 35 (optionally contacting or penetrating tissue below the perineal floor 35 such as the bulbar urethra, which is not shown, or urethra 8). The severed urethral stump tissue 27 is  
5 pushed against the severed surface 25 of the bladder neck to allow healing together and reconnection of the two severed tissue surfaces.

Figure 4 shows another example of a distal end of an approximating device of the invention. Distal end 40 includes a catheter body 42 with a proximal end 44 (not shown). The device includes a balloon 48, an inflation lumen 50 (partially shown), and a drainage  
10 lumen 52 (partially shown). Inflation lumen 50 extends within the catheter body 42 from the proximal end to the balloon 48, in fluid communication with the balloon 48, for inflating and deflating the balloon 48. The drainage lumen 52 extends from the proximal end 44 to the distal end 40 and to drainage apertures 46. One set of tines 54 is located on the distal end 40 of the device, retractably extending through catheter body 42, proximal  
15 to balloon 48. Tines 54 movably extend through apertures (not numbered) and in the general direction back toward the proximal end of the catheter body and away from the distal end. Another set of tines 56 is located at the distal end 40 of the device 40, but toward the proximal end of the device relative to balloon 48 and also toward the proximal end of the device relative to tines 54. Tines 56 movably extend through apertures (not  
20 numbered) and in the direction toward the distal end of the catheter body and away from the proximal end. Each set of tines 54 and 56 can be independently remotely operated, e.g., by using actuating connections 55 and 57 that extend through the catheter body 42 to the proximal end.

In use, when anastomosis device 40 of figure 4 is installed, balloon 48 is located  
25 inside of the bladder and tines 54 can be positioned at a position along the catheter body 42 so that when extended from the body 42, tines 54 penetrate into tissue for placing and preferably holding a severed tissue in place next to a corresponding severed tissue. As a specific example, tines 54 and 56 can be positioned along the catheter body 42 so that when extended from the body 42 during use, tines 54 penetrate into tissue of the bladder  
30 and tines 56 penetrate into tissue of the perineal floor, the opposing tines applying pressure to hold the severed urethral stump against the bladder neck.

Still another embodiment of an anastomosis device of the invention can have a single set of elongate tissue approximating structures, e.g., curved tines, that extend from a single position (i.e., a common distance from an end) along the length of a catheter body. The tissue approximating structure may extend through apertures and from the catheter body to contact a tissue, e.g., penetrating into the tissue and optionally through the tissue. An example is shown in figure 5. Figure 5 illustrates a distal end 60 of an exemplary anastomosis device of the invention, containing a single set of three curved tines 62. In use, when the anastomosis device having distal end 60 is installed, balloon 68 is located inside of a bladder and tines 62 can, for example, be positioned at a position along the catheter body 64 to extend from the catheter body 64 to penetrate first into and through tissue of the perineal floor, then into the bladder wall (see figure 5a). As a result, the single set of tines 62 can be effective to hold a severed bladder tissue in place next to a severed urethral stump. Tines 62 can be extended or retracted through apertures 66 in catheter body 64, using actuator 61. In this embodiment, the actuator 61 runs through a lumen along the length of catheter body 64 and splits into or connects to the three individual tines 62, which exit the catheter body 64 through apertures 66.

An alternative embodiment of anastomosis device could include a single set of tines that extend from the anastomosis device in the opposite direction from that shown in figure 5. Such an embodiment is shown in figure 6. Figure 6 illustrates an example of a distal end 70 of an anastomosis device according to the invention, containing a single set of curved tines 72. In use, balloon 78 is located inside of a bladder, and tines 72 can be positioned, for example, along the catheter body 74 to extend from the catheter body 72 to penetrate first into and through tissue of the bladder, then into and through the perineal floor (see figure 6a). Tines 72 can be extended or retracted through apertures 76 in catheter body 74 using actuator 71. In this embodiment, the actuator 71 runs through a lumen along the length of catheter body 74 and splits into or connects to the three individual tines, which exit catheter body 74 through apertures 76.

Alternate embodiments of anastomosis devices (and related methods) will be useful according to this description, as will be appreciated by those of skill, even if not specifically illustrated or described. For example, combinations of the above described features of an anastomosis device, as well as other features such as additional or different

structures or protrusions, can be useful to function as tissue approximating structures. Examples may include a second balloon (see, e.g., figure 7) or other movable, inflatable, or stationary structures. Additionally, the number or structure of the tissue approximating structure (e.g., tines) may be of any useful variation, as may be the mechanism by which  
5 a tissue approximating structure is actuated.

The catheter and its componentry may be made of materials normally used and known to be useful for such devices, or future developed materials, especially including known or future developed materials that are relatively inert and biocompatible. For example, a catheter body may be prepared from a flexible plastic or polymeric material.  
10 Examples of presently understood materials that may be useful for a catheter body can include silicones, latex, rubbers, polyurethanes, and combinations of these or other materials. A tissue approximating structure can be made from these or other materials, including relatively rigid plastics, polymers, or metals, optionally including bioresorbable materials such as bioresorbable polymers. Examples of metals include stainless steel,  
15 nitinol, titanium, tantalum, as well as alloys or combinations of these materials.

Optionally, portions or all of an elongate tissue approximating structure may be bioresorbable, if desired. This could allow for devices and methods that allow the bioresorbable structure (e.g., a bioresorbable tine) to remain in place after removal of the anastomosis device, after which the bioresorbable structure would resorb over time.

20 The tissue approximating structure can be actuated by any useful method or device or structure, for example as illustrated in the attached figures, by an elongate actuator mechanism extending through a lumen in a catheter body. The actuator mechanism may be of the same material as the tissue approximating structure, or may be a different material secured to the tissue approximating structure. The actuator may  
25 extend out of the proximal end of a device or may enter the device through a lateral port located at the proximal end of the device.

The device, in addition to the foregoing, may also include other mechanisms or features, as will be appreciated by those of skill. Examples include features such as a temperature probe or temperature reading mechanism. As one example of a specific  
30 feature that may be incorporated into a preferred embodiment of the invention, an actuator mechanism for a tissue approximating structure may be removable at an exterior

portion of the device. For example, an actuator mechanism may extend through a catheter body through an end or through a port at the proximal end of the device. The actuator mechanism or a portion thereof may be removably attached to the device and the tissue approximating structure, so that the surgeon can operate the tissue approximating structure while the actuator mechanism is attached during a surgical procedure, and the actuator may be removed following the procedure to avoid inadvertent actuation by the patient during the healing period, during which the device is still installed in the patient. When the time comes to remove the device, the actuator mechanism may be re-attached externally to uninstall the device.

10 In general, a catheter can be used during urethral anastomosis procedures such as that associated with a radical prostatectomy, e.g., vesico-urethral anastomosis, with the catheter functioning to remove urine from the bladder after the procedure. By ordinary methods, and according to the inventive methods described herein, an anastomosis device can be used by inserting the elongate flexible catheter body through the urethra and into  
15 the bladder. A portion of the distal end of the device becomes located inside of the bladder where the balloon can be inflated and where the drainage lumen can be used to drain the bladder and keep urine out of the bladder during and subsequent to the procedure. The bladder can preferably be drained of urine during the procedure and during the healing period following the procedure, because urine is preferably kept away  
20 from the site of anastomosis to facilitate healing, and also to prevent urine from creating pressure within the bladder.

A typical Foley catheter can include a drainage lumen and an inflation lumen for inflating and deflating the balloon. The balloon is normally deflated until properly positioned in a patient's bladder. Once the catheter is properly positioned, the inflation  
25 lumen delivers fluid to inflate the balloon. The inflated balloon can be used to hold the catheter in place, and, in embodiments of the invention, can also be used to draw the bladder and bladder neck toward the urethral stump and to hold the bladder in that position during healing of the bladder neck to urethral stump. Inventive devices and methods additionally allow for the use of other tissue approximating structures, such as  
30 tines, needles, probes, prods, balloons, etc., or combinations of these and other structures, to place severed tissue into contact and hold the tissues together for healing.

Figure 8 shows a single example of a modified-Foley-catheter-type anastomosis device according to the invention. Device 100 includes distal end 108, catheter body 102, balloon 104, and drainage aperture 106. Tissue approximating structure can be located along the catheter body 102, for example, as illustrated, along catheter body 102 approximately midway between the far ends of the device. (This location may be useful, for example, in performing an end-to-end urethral anastomosis procedure; a location closer to balloon 104 may be useful for a vesico-urethral anastomosis). Tissue approximating structure of device 100 is shown as a single set of tines 122 (shown in an extended position) but may alternatively include an additional set of (optionally opposing) tines, a different type of elongate structure such as a probe or prod or needle, a balloon, or any other structure that may be used to place or hold severed tissue in contact with another opposing severed tissue for healing.

Still referring to figure 8, device 100 includes proximal end 110 that includes a port 114 and that can be connected to attachment 112. Useful such proximal end and attachment configurations are well known, and such known or future developed proximal ends and attachments will be understood to be useful according to devices and methods of the invention. In the illustrated embodiment, proximal end 110 includes a port 114 that may connect to a lumen (not shown) such as an inflation lumen for balloon 104 or a drainage lumen from aperture 106. Another port, 116, part of attachment 112, can also be used with an inflation lumen or a drainage lumen. Connector 120 is part of an actuating mechanism for extending and retracting tines 122. Connector 120 may be attached to another portion of an actuating mechanism such as a turnable knob or a lever (not shown), etc., that can be moved or rotated to extend or retract tines 122. Other variations of these features of the illustrated attachment and proximal end will be understood by those of skill, and may be used in combination with the features of the present invention.

Generally, a method of the invention can include a step of performing a radical prostatectomy by a known or future developed technique, such as by a retropubic technique, a laparoscopic technique, or a transperineal technique. These techniques leave a bladder neck and a urethral stump for re-attachment. Prior techniques may use sutures or other mechanisms or structures that are separate from a catheter to re-attach the



severed tissue. The use of sutures or other such separate mechanisms or structures is preferably not necessary and most preferably avoided according to methods of the invention.

The distal end of the anastomosis device may optionally be partially installed  
5 during the prostatectomy procedure, e.g., up to the perineal floor, or may be installed to that point afterward. Following removal of the prostate, the catheter body of the distal end of the device is passed through the urethral stump and then through the bladder neck. From there, the technique can include inflating the balloon inside of the bladder, and using tissue approximating structure to place the severed tissue surfaces of the urethral  
10 stump and the bladder neck into contact for healing. A preferred step can also be to close the bladder neck to a desired size via a purse-string suture.

From this point, the steps and techniques used to actuate the tissue approximating structure and place the severed urethral stump and bladder neck tissue into contact for healing, can depend on factors that include the structure and actuating mechanisms  
15 associated with the particular anastomosis device that is used.

Common to all vesico-urethral techniques can preferably be to carefully avoid damaging sensitive tissues near the bladder neck and urethral stump. Specifically, ureters are proximal to the bladder neck and should not be contacted. Proximal to the urethral stump are sensitive nerves and a sphincter. Some of these tissue structures are generally  
20 regarded as being at the 5 o'clock and 7 o'clock positions of the bladder neck and the urethral stump. Advantageously, the devices and methods of the invention can afford significant opportunity to identify the location of these tissues, and position and re-position the tissue approximating structures to avoid them. As an additional feature of the device, markings can be made along a length of the outer surface of the catheter body,  
25 e.g., at the location of apertures from which elongate tissue approximating structures extend. A surgeon can view these markings when positioning the catheter body relative to a urethral stump and bladder neck, to avoid potential damage to sensitive tissue locations. Also in preferred embodiments, elongate tissue approximating structures such as tines or needles can be constructed and located to facilitate avoidance of sensitive  
30 tissues, such as by providing a set of three tines that radiate from a cross section of a catheter body at approximately 120 degree angles apart from each other.

Examples of steps to install tissue approximating structures can be described by reference to the figures. Referring to figures 2 and 2a, an example of steps for using the tissue approximating structure of the illustrated embodiment of the anastomosis device shown, can be as follows. Following inflation of balloon 26 inside of bladder 34, the bladder is pulled against perineal wall 14 (see figure 2a). Severed bladder neck surface 25 contacts severed urethral stump tissue 27, to allow healing with the device 20 installed. Optionally and preferably, another form of tissue approximating structure may be employed proximal to the perineal floor 14 to produce pressure from the perineal floor 14 against the bladder neck 24 and balloon 26. The additional form of tissue approximating structure may be in the form of a second balloon, or one or more elongate structures extending from the catheter body 21, through apertures, from underneath or at the level of the perineal wall 14. Figure 7, for example, shows a second balloon 80, which applies pressure to perineal floor 14, from below.

As another example, referring to figure 4a, following inflation of balloon 48 inside of bladder 34, the bladder is pulled against perineal wall 14. Severed bladder neck surface 25 contacts severed urethral stump tissue 27. Prior to or after pulling the bladder 34 to contact the perineal wall 14, a distal approximating structure in the form of tines 54 are extended from catheter body 40 and penetrate bladder tissue 34, carefully avoiding ureters (not shown) optionally by reviewing the position of tines 54 and repositioning or re-inserting the tines as necessary either by retraction of the tines or by adjusting the position of the catheter body 40 relative to the bladder tissue 34. Tines 54 may penetrate into or through bladder tissue 34, as desired. After pulling the bladder to contact the perineal wall 14, proximal tissue approximating structure in the form of tines 56 are extended from catheter body 40 to penetrate perineal wall 14. Again, sensitive tissue is carefully avoided with optionally review and re-positioning of tines. Severed bladder neck surface 25 contacts severed urethral stump tissue 27, to hold the severed tissue surfaces together to allow healing, while the anastomosis remains installed. Upon completion of the healing process, tines 54 and 56 are retracted back into the catheter body 40, and the device can be removed.

As still another example, referring to figure 5a, following inflation of balloon 68 inside of bladder 34, the bladder is pulled against perineal wall 14. Severed bladder neck

surface 25 contacts severed urethral stump tissue 27. Tissue approximating structure in the form of tines 62, proximal to the perineal floor 14 can be extended to penetrate into and through perineal floor 14, and then further penetrate into bladder tissue 34. Severed bladder neck surface 25 contacts severed urethral stump tissue 27, to allow healing, while the anastomosis remains installed. Upon completion of the healing process, tines 62 are retracted back into the catheter body 64, by use of actuator 61, and the device can be removed.

Figure 6a shows steps of another embodiment of a method and device of the invention. Following inflation of balloon 78 inside of bladder 34, the bladder 34 is pulled against perineal wall 14. Severed bladder neck surface 25 contacts severed urethral stump tissue 27. Tissue approximating structure in the form of tines 72, proximal to bladder tissue 34 can be extended to penetrate into and through bladder tissue 34, and then further penetrate into perineal floor 14. Severed bladder neck surface 25 contacts severed urethral stump tissue 27, to allow healing, while the anastomosis remains installed. Upon completion of the healing process, tines 72 are retracted back into the catheter body 74, and the device can be removed.

Figure 9 shows still additional embodiments of inventive methods and devices relating to a urethral anastomosis procedure below the perineal floor. Figure 9 illustrates device 90 having distal end 92 installed through perineal floor 14 and into bladder 34, through urethra 8 which passes through prostate 10. This procedure does not include removal of the prostate, but instead relates to severing and re-attaching urethra 8 at a point below perineal wall 14, e.g., re-attaching severed urethra portions 8a and 8b. According to the illustration, three tines 94 can be used to place surfaces of severed urethra portions 8a and 8b together, and hold them together for healing (see figure 9a). Specifically, tines 94, total six tines, three as a distal set of tines pointed approximately away from the distal end of the device and three as a proximal set of tines pointed approximately toward the distal end of the device. Each set, the distal set and the proximal set, is independently movable by actuating mechanisms 96 and 98 to retract or extend through apertures in catheter body 99. When installed, tines 94 are located along the catheter body 99 at a location that allows each set to contact a severed urethra tissue portion.

Figure 9a illustrates the extended distal and proximal sets of tines 94 extending into opposing portions of severed urethra 8 and holding the severed tissue portions 8a and 8b in contact for healing. The tines contact and move the portions together for healing. The installed device also includes a balloon in bladder 34 and drainage means that function together to cause urine to pool in the bladder and drain from the bladder. Thus, the illustrated device may be left installed, including the tissue approximating structure, during the healing period. As will be appreciated, other embodiments of the device may also be used in an end-to-end anastomosis procedure, such as other embodiments illustrated herein, including devices that include a single set of tines similar to the tines of figures 5 and 6.

Figures 9b and 9c are close-up illustrations of the tissue approximating structures of figures 9 and 9a, respectively, for clarity. As is illustrated in close-up figures 9b and 9c, tines 94 can be extended from catheter body 90 to penetrate into and optionally (although perhaps not preferably) through urethral tissue 8. The opposing severed urethral tissues are brought together (optionally with the assistance of the opposing tines) and are held together as shown in figure 9c preferably for a time sufficient to cause healing together of the severed tissues while the anastomosis device is installed and functions to drain urine from the bladder.

An anastomosis device as described herein can remain installed in the patient during the time required for healing of the two tissue surfaces together, during which time the balloon remains inflated to prevent urine from passing through the bladder neck. The healing period can be considered the time period taken for severed tissue to achieve a water tight anastomosis. The healing period can depend on many factors such as the type of operation and the patient, and can take, e.g., from possibly as little as one or two days, up to possibly two months, with periods of from two to four weeks being sometimes typical.

While the device is installed, urine accumulates and pools inside of the bladder and can be drained from the bladder, preferably through drainage apertures and a drainage lumen within the anastomosis device, flowing to the proximal end of the device for collection. Such preferred embodiments of the inventive devices and methods offers the advantage of providing a single anastomosis device that functions to allow the

severed tissue surfaces to heal together by use of the tissue approximating structure, without sutures, while at the same time providing a draining mechanism. The advantage of not requiring sutures for holding the severed tissues together or for healing can offer cost savings and eliminate complications by significantly reducing procedure time, thus  
5 reducing costs, and also reducing the length of time a patient is anesthetized. Sutures do not have to be removed, but instead, the tissue approximating structures of the anastomosis device can be retracted or deflated, and the device can be removed after healing.

Following is one series of more detailed exemplary steps useful according to the  
10 methods of the invention, for using the inventive anastomosis device to perform a prostatectomy.

1. Perform a radical prostatectomy by any method such as retropubic, laparoscopic, or transperineal, until prior to the vesico-urethral anastomosis. The following description is in the context of a retropubic radical prostatectomy, and with  
15 reference to an embodiment of the inventive device as illustrated at figures 4 and 4a.
2. Close the bladder neck to the desired size via a purse-string suture.
3. The AD can be inserted into the bladder prior to the suturing to help determine the desired size or the bladder can be sutured independently.
- 20 4. Insert the AD through the meatus until it exits the urethral stump in the open abdomen.
5. Pull the AD until enough length has been exposed to reach the bladder.
6. Insert the AD into the bladder and inflate the balloon.
7. Extend the top (distal) tines of the AD and visually ensure that the tines do not  
25 penetrate the ureters of the bladder. This can be facilitated by extending and retracting the tines and seeing the “bump” form on the exterior wall of the bladder. The AD may also have visual markers on the external wall of the AD proximal to the top tines to mark the location of the tines.
8. The bladder can then be lowered to the perineal floor by releasing the traction on  
30 the bladder and physically moving it down by hand while lightly maintaining tension on the AD.

9. Once the bladder has been drawn to contact the urethral stump, a light tension can be placed on the AD while the proximal tines are extended into the perineal floor.
10. The bladder can then be filled using the drainage port on the AD and the anastomosis site can be checked for leaks.
- 5 11. If a leak is experienced the AD can be repositioned until the desired performance is reached.
12. The AD can remain in place for a time depending on the healing needs of the individual patient.

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